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EXAMINER	
GECKLE, C	

ART UNIT	PAPER NUMBER
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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s); 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-52 are pending in the application.
   Of the above, claims 9 and 11-52 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-8 and 10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☑ Claims 1-52 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☑ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-8 and 10, drawn to a product, classified in Class 426, subclass 49.

II. Claims 9 and 14-19, drawn to a method of use, classified in Class 426, subclass 2.

III. Claim 11, drawn to an animal, classified in Class 800, subclass 2.

IV. Claim 12, drawn to a product, classified in Class 426, subclass 55.

V. Claim 13, drawn to a product, classified in Class 426, subclass 55.

VI. Claims 20-36 and 42-49, drawn to a process of making and a process of selecting by culturing, classified in Class 435, subclass 134 and Class 435, subclass 243+.

VII. Claims 37-41, drawn to microorganisms, classified in Class 435, subclass 243.

VIII. Claim 50, drawn to a method of treatment, classified in Class 514, subclass 560.

IX. Claim 51, drawn to a method of treatment, classified in Class 514, subclass 560.

X. Claim 52, drawn to a method of treatment, classified in Class 514, subclass 560.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product can be used in a materially different process such as preparing surfactants.

Inventions II and III are related as process and product by process. The process does not determine the patentability of the product. The groups are mutually exclusive of one another. No material difference is necessarily present in the claimed product and the product made by a materially different process.

Inventions II and IV and V are related similarly to the inventions above in terms of process and product by process.

Inventions VI and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the process can be used to make a materially different product such as proteins.

Inventions VII and II are related as product and process of use. The inventions can be shown to be distinct if either or

both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the microorganism can be used in a materially different process such as a process for producing proteins.

Inventions I, III, IV, V and VII are distinct and mutually exclusive products. The patentability of one does not rest on the patentability of another.

Inventions II, VIII, IX and X are mutually exclusive methods of use.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Brenda Speer on 1/30/91 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8 and 10. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9 and 11-52 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The claims are not written in proper format. Applicant is asked to refer to M.P.E.P 608.01(m) in regard to form of claims.

Each claim should begin with a capital letter and end with a period. Additional periods should not be used unless abbreviations are being designated.

Claims 1-8 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the recitation of "microorganisms or extracted omega-3 HUFAs" is vague and indefinite. The Markush group is confusing and improper. It appears that two different genera (microorganisms and fatty acids) are being claimed for one set of materials in the Markush group. A preferred recitation would be as follows: A food product comprising a source of omega-3 highly unsaturated fatty acids (HUFAs) selected from the group consisting of microorganisms from the order Thraustochytriales, omega-3 highly unsaturated fatty acids extracted from said microorganisms, and mixtures thereof; and ...

The recitation of "HUFAs" is vague and indefinite. Abbreviations should be defined in the first instance of use.

The taxonomic order Thraustochytriales should be underlined or italicized.

Claim 10 is vague and indefinite in its recitation. The claim is confusing as its dependency appears to incorrect. The claim is drawn to a food product which is dependent on a process claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8 and 10 are rejected under 35 U.S.C. § 102(a) as being anticipated by Long.

Long discloses the production of omega-3 fatty acids by heterotrophic microorganisms from the genera Thraustochytrium and Schizochytrium. Long also discloses the omega-3 fatty acids to be useful in nutrition as a nutritional additive to human diets as well as an animal feed additive. The reference reads on the claimed invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 4-7 are rejected under 35 U.S.C. § 103 as being

unpatentable over Long taken with Chang et al. and Traitler et al.

The claimed invention is drawn to a food product which contains omega-3 fatty acids from microorganisms from the order of Thraustochytriales and further consisting of an antioxidant.

The teachings of Long are discussed supra. Long fails to teach an antioxidant in the food product, extruding the food product or the packaging of the food product under non-oxidizing conditions. Chang et al. does however teach that the stability of omega-3 fatty acids can be increased with the addition of an antioxidant (column 3, lines 34-36). Traitler et al. teach protecting oils containing polyunsaturated fatty acids from oxidation by using antioxidants. Traitler et al. also teaches a nutritive composition which contains fatty acids which is extruded prior to solvent extraction. It would have been obvious to one of ordinary skill in the art to employ an antioxidant as taught by Chang et al. or Traitler et al. in a food product taught by Long and expect successful results in terms of improved stability. It would have also been obvious to one of ordinary skill in the art to apply a known technique such as extruding to a food composition taught by Long and expect successful results. The choice of the form of the microorganism (whole or lysed) as well as the means of packaging is a matter of judicious selection on the part of the ordinary artisan in optimization of conditions.

Claims 1-3,8 and 10 are rejected under 35 U.S.C. § 103 as being unpatentable over Ellenbogen et al. taken with Kyle.

Ellenbogen et al. teach the production of omega-3 highly unsaturated fatty acids from the genera Thraustochytrium and Schizochytrium (note table 1 on page 807). The reference fails to teach the use of this source of omega-3 fatty acids in a food composition. Kyle however teaches the screening, selecting, and improving of the yields of eicosapentaenoic acid (EPA) in microalgal species as a possible alternative to fish oil for a source of EPA in the food industry. Kyle provides the motivation to screen, select and improve culturing conditions to increase the yields of EPA in the microalga genera taught by Ellenbogen et al. as well as its application in the food industry.

Claims 4-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Ellenbogan et al. taken with Kyle as applied to claims 1-3,8 and 10 above, and further in view of Chang et al. and Traitler et al.

The same teachings of Chang et al. and Traitler et al. discussed above are relied upon it the instant rejection. It would have been obvious to one of ordinary skill in the art to utilize antioxidants as well as extruding methods as taught by Chang et al. and Traitler et al. in the food composition taught by Ellenbogan et al. and Kyle with a high expectation of successful results. The choice of the form of the microorganism (whole or lysed) as well as the means of packaging is a matter of

judicious selection on the part of the ordinary artisan in optimization of conditions.

No claim is allowed.

Any inquiry concerning this communication should be directed to Carol Geckle at telephone number (703) 308-0196.

DOUGLAS W. ROBINSON
SUPERVISORY PATENT EXAMINER
ART UNIT 188

Carol Geckle

February 7, 1991